Response to Public Comments

On

The Public Review Draft of the

Exposure Assessment and Stochastic Analysis Technical Support Document

February 2012

Comments Received from the Santa Barbara Air Pollution Control District

Comment 1:

Implementation of Weighting Factors for Early Life Exposures: The revised document includes new weighting factors to estimate cancer risk based on the variation in potency of carcinogens for exposure at different life states. Please explain how OEHHA recommends implementing these new weighting factors. Will the weighting factors be included in future versions of the HARP program? Will the user need to choose when to apply weighting factors and which to apply, or will the HARP program include the weighting factors automatically? Please provide recommended guidance on when and how the weighting factors should be used toxic risk management decisions.

Response 1:

The early in life weighting factors are explained in the *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures, 2009*. The early in life weighting factors are used when calculating cancer risk. Since exposure is greater early in life due to physiological and behavioral reasons, dose needs to be calculated separately for the different age ranges. The age ranges for early in life exposure are third trimester to <age2, age 2 to <16, and 16 to 70. OEHHA is recommending 9 years for average residential occupancy duration, 30 years as 95th percentile estimate and 70 years for lifetime residential occupancy duration. Therefore if cancer risk is to be calculated for a 30 year residency occupation duration, the following procedure needs to be used:

Calculation of Cancer Risk from Third Trimester to Age 30

ADD third trimester X CPF X 10 X 0.3/70 years + ADD age 0 to <2 X CPF X 10 X 2/70 + ADD age 2 < 16 X CPF X 3 X 14/70 + ADD age 16 < 30 X CPF X 1 X 14/70 years
ADD = Average Daily Dose
CPF = Cancer Potency Factor

The use of early in life weighting factors are the OEHHA recommended risk assessment procedures for calculating cancer risk for infants, children and adolescents, based on a scientific analysis of data on cancer potency of carcinogens with early in life exposure. These procedures are similar to those used by the U.S. Environmental Protection Agency. Since the general population includes infants, children, and adolescents OEHHA recommends that cancer risk calculated using the the early in life weighting factors be used in risk management decisions. The California Air Resources Board is responsible for developing the version of HARP that will incorporate the revised Hot Spots risk assessment guidance when endorsed by the Scientific Review Panel and

adopted by the Director of OEHHA. It is OEHHA's understanding from talking to the ARB that the early in life weighting factors will be incorporated into the algorithms of HARP so that these calculations can be performed readily.

Comment 2:

Implementation of Daily Breathing Rate Changes: The revised document includes new age specific breathing rates for use in health risk assessments. Please explain how OEHHHA recommends implementing these new breathing rates. Will the breathing rates be included in future versions of the HARP program? Will the user need to choose when to apply the different breathing rates and which to apply, or will the HARP program include the breathing rates automatically: Will the age-specific breathing rates be addressed in the same way that the weighting factors, specified in Comment 1 above are: Please provide recommended guidance on when and how the age-specific breathing rates should be used for toxic risk management decisions.

Response 2:

OEHHA recommends using the high end breathing rates to calculate cancer for risk management decisions because the high end breathing rates represent those at greatest risk in the population from the inhalation pathway. Should the breathing rate pathway not be among the top two pathways in a multipathway risk assessment, OEHHA would recommend using the average breathing rates for assessing inhalation cancer risk. It is our understanding from discussions with the ARB that the updated HARP program will automatically select the correct breathing rates in a multipathway, or inhalation pathway only risk assessment. The calculation of cancer risk using the average breathing rates should be a user specified option if the high end breathing rates are automatically used in the calculation of cancer risk. The new version of HARP is shaped by the HARP advisory committee which is open to participation by District representatives.

Comment 3:

Implementation of the 8-hour RELs: The revised document includes discussion regarding the new 8-hour RELs for use to assess chronic risks to workers and residents. As stated in the document, OEHHA has developed 8-hour RELs for some pollutants and will eventually develop 8-hour and chronic RELs for all chemicals as OEHHA completes its re-evaluation of RELs under SB-25. Please explain how OEHHA recommends implementing the 8-hour RELs. Will the 8-hr RELs be included in future versions of the HARP program: Please provide recommended guidance on when and how the 8-hr RELs should be used for toxic risk management decisions made by the District.

Response 3:

Although there is some explanation of the use of the 8-hour RELs in the Draft Exposure Assessment and Stochastic Analysis Document, OEHHA is adding text to cover the use of the 8-hour RELs in more detail. Note that the 8-hour RELS are meant for those scenarios where exposure to receptors near the site would approximate a work day (e.g. offsite worker scenario). Please see…..

Comment 4:

Crystalline Silica: Although not specifically discussed in the Technical Support Document for Exposure Assessment and Stochastic Analysis document, the District would like a recommendation from OEHHA on how to implement the Crystalling Silica toxic risk factors. OEHHA established a non-cancer health benchmar—a REL –of 3µg/m3 for crystalline silica of PM4 emission factors. Please explain how OEHHA recommends evaluating the toxic risk from crystalline silica for risk management decisions with the absence of PM 4 emission factors.

Response 4:

OEHHA does not have a specific recommendation for implementation. The District may wish to consult with ARB about appropriate monitoring procedures. OEHHA does not have expertise in monitoring. One possible approach if routine PM 4 measurements are impractical would be to research the relationship between PM 4, PM 2.5, and PM 10 measurements at specific sites of interest. A fudge factor could be developed that related the routinely available methodologies for measuring PM 2.5 and PM 10, to methods for measuring PM 4. It could be that most of the PM 4 mass is contained within the PM 2.5 fraction, or that the PM 4 mass is close to the PM 10 mass (e.g. a small fraction of the PM 10 mass is between 4 and 10 µm). Note that the REL for crystalline silica is based on occupational studies, which measured exposure at PM 4using typical industrial hygiene samplers.

Comments from the County Sanitation Districts of Los Angeles County

General Comments

Comment 1:

Several of our facilities are required to submit health risk assessments under the AB 2588 program, and health risk assessments are required under several new source review regulations. We are concerned that the proposed modifications will exaggerate calculated risks from our facilities despite a continuing track record of emissions reductions. Moreover, we are concerned that the underlying research may be insufficient to substantiate the proposed methodology. Accordingly, we respectively request that additional r research be performed to validate the proposed methodology prior to its implementation.

Response 1:

The science of risk assessment changes over time as new studies become available. The Exposure Assessment and Stochastic Analysis Document was adopted in 2000. Since 2000, a large volume of peer reviewed literature has been published in the field of exposure assessment and fate and transport modeling. Estimated risks can go up or down as new information becomes available. The revised document will undergo legally mandated independent peer review by the state's Scientific Review Panel on Toxic Air Contaminants to help ensure that the proposed methodology is scientifically valid.

The proposed methodologies in the Exposure Assessment and Stochastic Analysis are similar to those used the USEPA Exposure Factors Handbook (2011). OEHHA does not for the most part conduct original research and is reliant on the published body of literature. The comment that the underlying research may be insufficient to substantiate the proposed methodology is very general in nature and is thus difficult to respond to without specific examples.

The Exposure and Stochastic Analysis document will allow implementation of the early-in-life weighting factors that will tend to increase estimated cancer risks. However, the Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures already went through the public review and the peer review process and was adopted by OEHHA in (May 2009), and is thus beyond the scope of this public comment period.

Comment 2:

Due to the limited public comment period and minimal notice regarding the public hearings, we believe that OEHHA should extend the public review process to allow greater outreach on this dramatic alteration of health risk procedures for the State of California.

Response 2:

OEHHA extended the 60 day public comment period for one week in response to this and other requests. A 60 day public comment period is fairly standard for many of our risk assessment documents. Several members of the Los Angeles County Sanitary Districts attended the public workshop in Diamond Bar.

Specific Comments

Comment 3:

Examples should be included to provide side-by-side point risk calculations using the old exposure indices vs. the proposed ones. Such examples are absolutely essential for decision makers and the public to comprehend the direct impact of the proposed methodology changes. An Executive Summary before Chapter 1 of the main document that addresses this comparison should also be provided to

help in this regard. We are concerned that facilities could be perceived as increasing pollution levels, while in the fact, the opposite may be occurring. A facility could have substantially lowered its emissions, and yet be identified as causing an increase in risk. A clear statement of this possibility should be included in the proposed Executive Summary.

Response 3:

OEHHA will include a summary of the proposed changes in the Scientific Review Panel Draft. We can include a statement that estimated risks may go up or down without any changes in emissions simply because the science evolves and the proposed methodology, which includes newer science is different than the existing methodology. The cancer and noncancer risk comparison calculated under the current methodology and the proposed new methodology is beyond the scope of what can be included in the Executive Summary. The noncancer inhalation risk calculations are based on dividing the acute, chronic, or 8-hour References Exposures Levels by estimated air concentrations. The recommended air modeling program has changed in the proposed Exposure Assessment and Stochastic Analysis document which might make some difference in the estimated ground level air concentrations depending in part on the particular site. As RELs are revised the estimates on noncancer risk for various chemicals have and will be adjusted up or down.

Cancer risk estimates from the inhalation pathway are likely to go up by a small factor depending on the size of the facility. However, a good portion of any increases in calculated cancer risks are due to adoption of the early in life weighting factors. The early in life cancer potency adjustments were adopted in 2009 (*Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures*) and are thus beyond the scope of public comment on the Exposure Assessment and Stochastic Analysis Document.

Cancer risk estimates from other pathways will vary between the existing methodology and the proposed methodology according to the chemical and the pathwayby which exposure is expected to occur.

Comment 4:

As suggested above, we request that OEHHA provide fact sheets to clarity and explain to the general public that the proposed methodology alone will result in significant increase in calculated health risks.

Response 4:

The local agency, in this case the local Sanitation District, is generally responsible for risk communication messaging to the public. OEHHA is generally available to provide advice on the messaging if the local agency requests assistance. The Sanitation District could do the side by side comparison using the older and newer versions of HARP to make their point.

Estimated risks for some chemicals, particularly noncancer risks, may appear to decline with the same emissions for some chemicals.

Comment 5:

We ask that OEHHA take this opportunity to further the public's ability to weight these risks in context with examples that may better resonate with the public consciousness that infrequent and disperse industrial exposures. For example, many people do not realize that activities associated with consumer products, indoor air quality (e.g. Radon), dietary habits, normal exposure to the sun, etc. create substantial health risks. These risks are often far in excess of those from industrial sources. We believe such examples will provide perspective for the public.

Response 5:

OEHHA would be happy to consult with the Sanitary Districts when they craft their risk communication messages. There is an extensive literature on risk communication and public risk perception that may be helpful in crafting your messages. There are also courses available. OEHHA has encountered many challenges in risk communication in various forums. In general, we avoid any comparison of voluntary activities such as smoking, diet, and exposure to the sun with involuntary exposures from industrial emissions. We have occasionally mentioned with mixed success the background incidence of cancer. It may be useful to point out the background cancer risk from air pollution in the Los Angeles basin is from about 1,400 to 2,000 in a million, mainly from diesel exhaust (MATES III Study). The Sanitary Districts provide the single most effective public health advance in human history, protecting the public against water borne disease, and it would be good if the public could be brought to view their air emissions within that context.

Comment 6:

A simple table showing a single age-weighted breathing rate against percentiles similar to Table 3.23 in the previous (year 2000) version of the draft TSD would be beneficial to those calculating Tier 1 point estimate risks.

Response 6:

Unfortunately the early in life exposure cancer potency adjustments make a combined breathing rate distribution useless for cancer risk calculations. The average daily dose needs to separately calculated and then multiplied times the cancer potency factor and the appropriate early in life adjustment factor. This is an example calculation for 30 year risk:

Calculation of Cancer Risk from Third Trimester to Age 30
ADD third trimester X CPF X 10 X 0.3/70 years + ADD age 0 to <2 X CPF X 10 X 2/70 + ADD age 2 < 16 X CPF X 3 X 14/70 + ADD age 16 < 30 X CPF X 1 X 14/70 years

ADD = Average Daily Dose
CPF = Cancer Potency Factor

We will revise Chapter 1 to include this information.

Comment 7:

Staff mentioned in the public workshop that much of the underlying data was sources from studies that inadequately characterize the populations of interest in California. Nevertheless, the changes OEHHA is proposing will radically change how health risk assessments are performed. Such sweeping changes should not be based on incomplete information.

Response 7:

This comment lacks specificity or examples and is thus difficult to respond to. Staff at the workshop pointed out some of the uncertainties and data gaps in risk assessment. These uncertainties and data gaps are not unique to California risks assessment, or the proposed Draft Exposure Assessment and Stochastic Analysis Document relative to the previous version. The specific example of the fish consumption variate cited at the workshop is not likely to impact Sanitary District risk assessments.

The exposure, and fate and transport variates, proposed in the Draft Exposure Assessment and Stochastic Analysis Document do not radically change how risk assessments are performed. In fact, some of the new exposure variates, based on newer studies, tend to lower estimated exposure and thus cancer risk. This revision of the Exposure Assessment and Stochastic Analysis has reduced uncertainty because of newer better data on a variety of the variates for both exposure, and fate and transport.

As mentioned previously, the early in life exposure weighting factors which do tend to increase estimated cancer risks are already approved, and not part of the Exposure Assessment and Stochastic Analysis document. However, the variates for age ranges required to apply the early in life exposure factors are made available in this document.

It is worth noting that the USEPA has adopted a similar scheme of early in life exposure adjustment factor for determining cancer risks, and is currently determining the list of chemicals to which they will be applied. Comments on the early-in-life weighting factors are beyond the scope of the public comment period on the Exposure Assessment and Stochastic Analysis Document.

Comments from the National Resource Defense Council

Comment 1:

Evaluation of Exposures from Multiple Sources of Air Toxics

Both the US Environmental Protection Agency (EPA) and the National Academy of Sciences (NAS) have highlighted the importance of including cumulative risk in risk assessments and risk-based decision making. 2 In EPA's most recent report on the subject, titled *Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document,* cumulative risk assessments are defined as including "aggregate exposures by multiple pathways, media and routes over time, plus combined exposures to multiple contaminants from multiple sources."

3 While OEHHA has made great strides in including assessments of multiple pathways and multiple chemicals in the exposure guidelines, cumulative exposures of air toxics from multiple facilities continue to be omitted. Many communities in California are exposed to emissions of air toxics from multiple sources. As pointed out in a Science Advisory Board's review of EPA's air toxic risk assessment procedures, "[a] risk analysis that does not add exposures to baseline contamination to the estimates of on-going contamination may vastly underestimate the hazard quotient at the site and incorrectly conclude that the on-going releases pose risks at less than threshold levels."4 The failure to include an assessment of risk from the aggregate exposure to emissions from multiple sources of air toxics jeopardizes the validity of the health risk values calculated using the Air Toxics Hot Spots Risk Assessment Guidelines and limits the ability of the Hot Spots program to identify and reduce the true health risks associated with air toxics in California.

OEHHA should revise the draft Guidelines to include an estimate of risk based on the aggregate levels of air toxics experienced by the maximum exposed individual. The absence of this assessment constitutes a very large uncertainty in the current exposure assessment methodology, which could result in significant underestimate of risk, and should be identified as such.

Response 1:

The Exposure Assessment and Stochastic Analysis Document includes information that can be used to assess cumulative risks, but the Hot Spots legislation AB-2588 and statute addresses risk from individual facilities. AB-2588 is a public-right-to-know act. Section 44362 B states:

> "Upon approval of the health risk assessment, the operator of the facility shall provide notice to all exposed persons regarding the results of the health risk assessment prepared pursuant to Section 44361 if, in the

judgment of the district, the health risk assessment indicates there is a significant health risk associated with emissions from the facility. If notice is required under this subdivision, the notice shall include only information concerning significant health risks attributable to the specific facility for which the notice is required. Any notice shall be made in accordance with procedures specified by the district."

Clearly emissions from individual stationary facilities contribute to overall air pollution levels and control of emissions from individual facilities tends to reduce aggregate air pollution levels. However, unless AB-2588 is modified to include consideration of cumulative impacts, this legislation is not designed as a primary tool in addressing cumulative impacts. Hot Spots risk assessments are clearly only addressing, and are only intending to address pollution from the individual facility. In urban areas such as Los Angeles, the cumulative risk from general air pollution will almost always dwarf the risk from an individual facility. The Hot Spots program has, however, been very effective in reducing emissions from stationary facilities and identifying classes of facilities that pose the greatest public health threats. Air Toxics Control Measures have subsequently been developed and applied industry wide to many of these facility types.

OEHHA encourages risk managers in the Hot Spots program to consider cumulative impacts and environmental justice concerns in their decisions. OEHHA participated in the development of the Cal/EPA document Air Quality and Land Use Handbook: A Community Health Perspective (April 2005) that addresses the air quality impacts of land use decisions.

OEHHA is concerned with cumulative risks from multiple sources and has produced a document, Cumulative Impacts: Building a Scientific Foundations as part of our efforts to address this issue. OEHHA is also the lead agency in a multiagency effort to address cumulative impacts. The agencies involved include, the Department of Toxic Substances Control, The Water Board, and the Department of Pesticide Regulation. The ARB has done pioneering studies in Barrio Logan in San Diego and Wilmington in Los Angeles County, as part of their Neighborhood Assessments Project.

The Hot Spots Analysis and Reporting Program used to perform risk assessments in the Hot Spots program can be used to assess the risk from multiple facilities and roadways, even though mobile sources are not part of the Hot Spots program. Studies such as the MATES III air monitoring and modeling study in the Los Angeles provide a picture of the risks from general overall air pollution from both mobile and stationary sources.

Comment 2:

Assessment of Variability in Facility Emissions

Although OEHHA has improved the exposure assessment guidelines to include assessment of variability in intake rates (e.g. inhalation rates, soil ingestion, food consumption), the continued reliance on single point estimates of facility emission levels is misleading and could potentially result in a significant underestimate of exposure. Given the daily and yearly variability in air toxic emissions from facilities, the use of a single estimate of the annual average and maximum 1-hour emissions is not sufficient to characterize the exposures in downwind communities. Facility emissions estimates should be treated similarly to the other exposure variates and the degree of variability and representatives of the values used in the air dispersion model should be explicitly evaluated and described. In the case of emissions of persistent and/or bioaccumulative contaminants, long term exposure estimates based solely on an annual average could significantly underestimate exposures if the pattern of emissions consists of intermittent, or periodic, spikes in emissions. These spikes in emissions may not be captured in the annual average emission level but could result in significant deposition resulting in an increased contaminant burden in the surrounding environment not evaluated in the risk assessment. As such, estimates of dietary, soil ingestion, and dermal exposure resulting from emissions of these contaminants, including metals, dioxins, and PAHs, could systematically underestimate actual exposures.

OEHHA should revise the draft Guidelines to include an explicit evaluation of the variability in emissions of air toxics used as the basis for the exposure assessment. In the case of persistent and/or bioaccumulative contaminants, the degree to which annual average emission levels adequately characterize intermittent spikes in emissions must be evaluated and accounted for in the exposure assessment. For non persistent contaminants, the suitability of comparison to the chronic REL for exposures to intermittent spikes in emissions should be evaluated.

Response 2:

The air modeling protocols for the Hot Spots program are under the purview of the Air Resources Board and the Districts. OEHHA does not have air modeling expertise on our staff. The air modeling protocols specify that at a minimum, the air concentrations of toxicants, cancer and noncancer risks at the maximally exposed residential receptor, maximally exposed offsite worker, the point of maximum impact, and evaluation at sensitive receptor sites such as schools, senior living facilities, day care facilities, and hospitals.

The cancer and noncancer risks at these points are meant to capture the highest risks in the community, and risk management decisions are usually based on protecting individuals at the highest risk points. Evaluation of these receptors for acute, chronic, and cancer risk is required. The locations of the individual receptor points may be different for the acute, chronic, and cancer endpoints, if a mixture of chemicals is emitted from the facility, particularly from multiple stacks. In addition the Exposure and Stochastic Analysis document specifies that the acute hazard index, chronic hazard index, and cancer risk isopleths are provided on a map with the facility and surrounding area. In summary, specific information on air concentrations and acute chronic and cancer risks, for typically at least three receptor points, and in some cases additional sensitive receptors is provided. In addition, information on the range of risk throughout the affected community is provided by the risk isopleths.

The ideal meteorological data set for a Hot Spots risk assessment would be at least a year of onsite data. However, the cost of collecting such data is considerable and therefore reasonably representative meteorological data sets have been identified by the Districts and approved for use at a particular facility. If the topography is different at the facility, the use of offsite meteorological data can introduce considerable uncertainty. A qualitative description of the uncertainty in the location and air concentrations at receptor points would be typically all that could be done to address these uncertainties.

Most Hot Spots risk assessments are based on emissions factors that rely on estimates of pollutant emissions from various industrial process and throughput calculations. These emissions estimates are selected so that emissions will tend to be overestimated rather than underestimated, in the interest of public health protection. Estimation of the variability in hourly emissions from industrial processes is not generally available. Real time stack monitoring would probably be required and it is not clear that currently available air modeling computer programs could translate this information into estimates of variability in ground level concentrations due to emissions.

Real time monitoring methods also tend to be insensitive and only available for a limited array of chemicals. Apart from variability in emissions, variability in exposure concentrations within an annual average is an expected outcome simply due to shifts in wind direction and speed, differences in nocturnal vs. diurnal wind patterns, and seasonal variation in the meteorology. This is the reason that at least a year's of worth of meteorological data, and preferably several years is needed to characterize an annual average.

Chemical toxicity can be due to total accumulated dose, or exposure concentration or a combination of both. Often the toxicity studies upon which chronic RELs are based, and /or mechanistic studies do not allow a clear determination of the relative contribution of concentration and total dose to the toxic endpoint. Studies of industrial chemicals exploring the toxicological

significance of chronic exposure to the same dose through multiple spikes throughout the day compared to constant exposure are not available to our knowledge. Thus even if minute to minute information could be collected on toxicant ground level concentrations, the toxicological significance would be unknown.

The significance of such an exposure pattern would have to be determined on a chemical by chemical basis and such research is not likely to be forth coming in our opinion. The toxicological significance of exposure to infrequent one hour concentrations of chemicals is addressed by OEHHA's acute RELs. If the average daily dose was, for example, delivered over a single short period of time, there could be cause for concern; however, such an exposure pattern from an industrial facility would be unusual.

The protocols for modeling deposition in the Hot Spots program are health conservative with regard to particle size assumptions and other parameters. It is not clear to us why emissions of persistent bioaccumulative chemicals would be underestimated if they occurred in multiple spikes andare modeled as an annual average deposition, as long as the annual average emissions were not underestimated.

Comment 3:

Improved Characterization of Breast Milk Exposures

The evaluation of exposures via ingestion of breast milk is an important addition to the draft Guidelines to ensure the characterization of all relevant exposure pathways. However, the list of contaminants for which this pathway is to be evaluated does not include all air toxics for which there is evidence of exposure through breast milk ingestion. Inhalation exposure to volatile organic compounds (VOCs), including benzene, toluene, and tetrachloroethylene (TCE), have been found to result in elevated levels of these compounds in breast milk.5 6 OEHHA should amend the draft Guidelines to include a discussion of other air toxics which could result in exposure to infants due the ingestion of breast milk. For those contaminants for which the appropriate transfer coefficients are unavailable, OEHHA should explain that omission of this route of exposure represents a source of uncertainty that potentially underestimates exposures to infants.

Response 3:

The breast milk pathway has been evaluated in the Hot Spots program from the inception of the program and is thus not a new addition. The current draft of the Exposure Assessment and Stochastic Analysis document add PAHs and lead to the list of chemicals for the pathway. As the commentator points out there, volatile organic chemicals can be measured in breast milk. OEHHA has examined the issue of volatile organic chemicals (VOCs) in breast milk, and we

recognize that the breast milk pathway can be a significant source of infant exposure in women exposed in the workplace. It is possible that transfer coefficients could be developed for some VOCs so that the toxicant dose that the mother transfers to the infant could be quantified. However, the risk assessment model used in the Hot Spots program assesses the inhalation pathway to the infant, and the dose that the infant receives through direct inhalation of VOCs during the period of breast feeding is considerably greater. Our model assesses inhalation up to age thirty for the infant and thus any dose received through breast feeding becomes even more insignificant.

In short, our analysis indicated that the dose from breast milk was insignificant relative to the inhalation pathway for the offspring. This clearly would not be the case with lactating women exposed to much higher concentrations in the workplace, which would transfer a much large dose through the breast milk pathway. The infant would not be exposed at all by inhalation pathway in this scenario (except by VOCs exhaled by the mother) because the infant would not be present in the workplace. The dose and risk could be quite significant in this scenario.

The chemicals where there is significant exposure to the infant through mother's milk are those where the chemical accumulates in the women's body over time. Dioxins and furans, and PCBs are poorly metabolized, fat soluble, and very slowly eliminated. Lead is stored in the bone and very slowly eliminated. Lead is mobilized from the bone by both pregnancy and lactation. PAHs are fat soluble, are subject to significant metabolism and elimination, but also are stored in fat. These chemicals have a long half-life (years) in the mother's body and the stored dose, partitions into the breast milk fat, and thus the infant receives the mother's accumulated store of these toxicants.

These chemicals of significance in this pathway are poorly metabolized (except PAHs), are not excreted from the mother's body through exhalation. VOCs in contrast partition into the mother's body fat but would reach a rapid equilibrium with atmospheric concentrations though inhalation and exhalation. Thus the fat concentrations of VOCs available for transfer to infants over the short period of breast feeding is quite small under conditions of low level chronic environmental exposures compared to the dose that infant, later child and finally adult receives by inhalation in our model.

OEHHA developed models for the breast milk pathway for PAHs and lead. To our knowledge these are first available models for these chemicals. We also developed more refined models for PCBs, dioxins and furans. The selection of chemicals for evaluation with the mother's milk pathway is determined by the physical-chemical properties of the chemical, metabolism and elimination, half-life in the mother's body (e.g. does the mother store the chemical in her body), public health significance of the potential exposure, and the availability of data to develop the model.

Comment 4:

Additional Discussion of Exposure Variates for Young Children

The inclusion of exposure variates for the 3rd trimester and childhood age groupings is an important addition to the draft Guidelines to improve the assessment of early-in-life exposures to air toxics in California. This assessment could be improved by providing greater granularity in the age groupings so as to better differentiate between the exposures of young, preschool aged, and older children. The 2 to 9 year old age category included in the draft exposure guidelines includes a wide range of behavioral and other exposure parameters potentially more due to differences in age than to inter-individual variability. Therefore, high end exposures to sub groups within this category may be masked and the 95th percentile may represent a mean for a sub-group. This could be of particular concern when evaluating risks to pre-school or early-childhood centers where the population at risk would occupy a smaller subset of this age category.

OEHHA should include in the Guidelines a discussion of the uncertainty in exposure estimates due to the artifice of the age groupings and update the categories as additional exposure variate information becomes available.

Response 4:

OEHHA created these age groupings to match the age groupings to which the cancer weighting (age sensitivity factors) are applied. Breaking out the age groupings out further would not appreciably change the cancer risk estimates for early in life exposures. Granular variates (narrower age grouping for a variety of variates are available in the US EPA *Exposure Factors Handbook (2011)* for those who need to assess risk for narrower age groupings. In general, the uncertainty in the exposure model is far less than for the dose-response part.

Comments from Dr. Kenneth Bogen, Exponent

Comment 1:

None of the atmospheric dispersion models cited in the proposed revisions is designed to estimate 2nd-order (i.e., variance- or intensity-related) aspects of modeled air concentration: they predict only average (i.e., expected) concentration contours. Consequently, the proposed revisions do not address substantial magnitudes of short-term-hazard threat-zone-size underestimation that are expected, due to reasonably anticipated magnitudes of spatiotemporal concentration fluctuation, for those respiratory toxicants (e.g., hydrogen cyanide, hydrogen sulfide, and chlorine gas) that have a toxic load exponent substantially

greater than one. This issue is the focus of the publication

Bogen KT, Gouveia FJ. Impact of spatiotemporal fluctuations in airborne chemical concentration on toxic hazard assessment. J Hazard Mater A 2008; 152(1):228–240.

that is attached in pdf form. This paper also cites a number of previous publications that have raised, addressed, and explored this issue over the last two decades.

Response 1:

It is true that the recommended air dispersion models for the Hot Spots program cannot evaluate acute intervals shorter than one hour. The one hour intervals can include air concentrations higher or lower than the estimated one hour average. The Hot Spots program addresses routine industrial releases not emergency accidental releases. The maximum one hour air concentrations modeled are predictions of maximum one hour air concentrations resulting from meteorological conditions, and worst case emissions from upset or startup conditions when appropriate. For accidental emergency emissions other air modeling approaches might be more appropriate.

Comments of the Western States Petroleum Association

Comment 1:

Dermal dose and exposure

We concur with the revised dermal equation. We see that this equation both, i) simplifies the calculation of the dermal dose, and ii) develops improved exposure estimates by determining a high-end estimate for four exposure variates combined (i.e., surface area, body weight, soil loading, and exposure frequency) instead of using high-end estimates for each individual variate. In addition, derivation of an Annual Dermal Load for warm, mixed, and cold climates provides a refined approach that considers the diversity in climate throughout the state.

Response 1:

One of the purposes in revising the Exposure Assessment and Stochastic Document was to make use of the advances in risk assessment since the previous version in 2000. Data on the variability in these exposure variates made it possible to refine the approach to dermal exposure.

Comment 2:

Residential and worker exposure

We support the proposed changes to the default values for exposure duration for a resident and worker. As noted in the TSD, a 30-year residential exposure duration is a reasonable estimate of the 90th or 95th percentile of residence time. Similarly, for the worker, 25 years represents a reasonable estimate of the 95th percentile for employment tenure. These proposed values are also consistent with the default values used under many other regulatory programs.

The term fraction of time at home (and away from home) is an important change that recognizes residents are not in their homes 24 hours a day. This, in turn, allows for more representative estimates of exposure and associated risk. As noted below, it would be helpful if further clarification were provided as to how this term is used in exposure algorithms.

Response 2:

Data available since the previous version of the Exposure Assessment and Stochastic Analysis Document allowed OEHHA to refine our estimates of residential exposure duration, employment tenure and activity patterns. There is an explanation of how the fraction of time away from home is to be applied in Chapter 11. We will review the explanation and provide more detail.

Comment 3:

The derivation of breathing rate point estimates to be applied for exposures of less than 24-hours per day (e.g., for 8-hour) is unclear. a. The title of Table 3.29 – *Hourly Breathing Rate (L/kg-Hour) Point Estimates for estimating Breathing Rates During the School Day)* – suggests that the information in the table would be applied only for school sites. However, discussion in the text (and at the December 2011 workshop) suggests that this information should also be used to derive breathing rates for off-site workers or for neighborhoods near facilities for which emissions occur only during the day.

It is also unclear how to translate a 1-hour breathing rate to an 8-hour (or other exposure time) breathing rate for a school child, off-site worker, or other receptor. Specifically, only two activity levels are identified: “sleeping and napping” and “moderate intensity activities.” A significant portion of waking hours are also spent at “light intensity activities,”for which breathing rates have not been included. Further, information on time-activity patterns is needed to estimate an 8-hour breathing rate using the hourly breathing rates. It would be overly conservative to assume that an entire 8-hour (or other) period during the day is spent at a “moderate activity” level, particularly if the 95th percentile value is recommended.

Response 4:

OEHHA will clarify the application of the breathing rates for offsite workers in Chapter 1. OEHHA has added a heavy intensity and light intensity breathing rates so that a greater range of worker breathing are available for different occupations..

Comment 5::

In addition, it is clear that a significant component to the fraction of time at a "residence", is the proportion of indoor (residential) vs. outdoor (ambient air quality) exposure. It is well documented that outdoor air is not well correlated with indoor air (at least based on centralized ambient air monitors) and is very poorly correlated with personal exposure. Indeed, indoor air quality is a function of ventilation (e.g., open windows, air conditioner use, building construction) and a myriad of other activities such as cooking or cleaning. Many studies show that it too is poorly correlated with personal exposure. Thus, ambient monitoring data for hot spots concentrations may have no bearing on exposures in a residence. In order to avoid overestimating exposure levels, OEHHA could consider adding factors to the exposure model to account for time spent outdoors while at the residence, time spent indoors at the residence, a factor for outdoor to indoor air penetration, and a factor for the difference between indoor air pollutant concentration and personal exposure levels.

Response 5:

It is true that indoor air concentrations may not be well correlated with outdoor air concentrations. Further i concentrations of chemicals found in the outdoors may be lower than the same chemical indoors due to indoor emission sources. However, the purpose of the Hot Spots program is provide a "public right to know" concerning emissions and risk from stationary facilities in the proximity of residents and offsite workers. Since the ultimate source of indoor air is outdoor air, the assumption that the modeled annual average concentration of indoor air from facility emissions would be reflected indoors appears to be valid.

Factors for indoor air penetration, accounting for indoor air pollutant concentrations and attempting to estimate personal exposure levels are valid academic questions but are not particularly relevant to the purposes of the Hot Spots program, are fairly unresolved, and therefore not included in the risk assessment model. The Hot Spots program does not utilize ambient monitoring data; air concentrations are modeled from facility emissions data.

The Hot Spots program also evaluates maximum one hour air concentrations at the PMI, residential MEI and worker MEI. It is possible that the indoor air concentrations with the maximum one hour concentrations could be lower

indoors but since a variety of factors such as windows are open or closed would influence the indoor concentration vs. the modeled outdoor air concentration, it is difficult to suggest a way of accounting for what could be a widely variable discrepancy. The resident or worker could also be outside at the time of the modeled maximum one hour concentration, therefore it is public health protective to simply assume the modeled maximum one hour represents the exposure concentration..

Comment 6:

Fraction of time at residence.

It would be helpful to show the equation for estimating inhalation exposure using the term for fraction of time at residence. That is, does this term replace "exposure frequency" (default of 350 days per year) used in the current equation? It is unclear if the term includes time away from home while at school (for children) or for an adult, time away from home while attending to activities such as shopping or at a workplace. Finally, it would be helpful to understand if OEHHA intends to apply this term fraction away from home only to the inhalation pathway, or if would be applied to the multi-pathway analysis as well.

Response 6:

The time away from residence includes all time away from home including vacation. OEHHA does not intend to apply the time away from residence to the noninhalation pathways. It is not clear how time away from residence would affect exposure from these pathways. For example, exposure through consumption of homegrown produce and home raised meats, or eggs would not appear to be affected by time away from the residence. The fraction of home raised produce, cow's milk, eggs, and meats presumably takes into account time away from residence.

Exposure through the soil ingestion and dermal pathways could well be predominately associated with activities carried out at the residence (i.e. afterschool play and gardening). The mother's milk pathway in terms of infant time away from the residence may not be affected at all. OEHHA is not aware of any data to shed light on the impact of time away from the residence on noninhalation pathways, therefore the public health protective approach is to assume that time away from residence does not affect exposure through the noninhalation pathways.

Comment 7:

Third Trimester Exposure Factors

The exposure assumptions for the third trimester do not take into account any modification of exposure by maternal factors. We would hope that the default assumptions that have been proposed can be replaced with compound specific information on absorption and distribution when available. It may be useful to conduct a sensitivity analysis of the exposure assumptions that are used for this time period.

Response 7:

The exposure assumptions for the third trimester do ignore the fact that exposure to the fetus is likely to be different than that of the mother for a variety of reasons. Constructing a Physiologically Based Pharmacokinetic model for each chemical in the Hot Spots program in order to more accurately estimate the dose to the fetus would be a monumental task for which OEHHA lacks the resources.

Further, sufficient data are lacking to construct such models for many chemicals. The overall contribution to a seventy, thirty, or even a nine year cancer risk from this three months period is relatively small and therefore the overall risk estimates for these exposure durations are pretty insensitive to the assumptions made for third trimester dose.

Comments and Response from EPA (Kim Hoang)

General Comments and Responses

Comment 1:

For the tier assessment, some other potential improvements would be to actually consider not only the point estimates and distributions, but also to consider actual site exposure conditions and scenarios, including all site specific exposure factors and pathways, instead of just the default exposure scenarios.

Response 1:

Site-specific estimates of exposure using site specific variates, or distributions, can be performed by facilities in Tier 2 and Tier 4 risk assessments, respectively, as discussed in Chapter 1. The assessor would need to provide clear, reasonable justification in the risk assessment for using alternative distributions or point estimates.

Comment 2:

Essentially, the direct exposure pathways considered in this Draft document includes breathing in Air emission, or drinking surface water and touching the soil contaminated with air deposition. All the other pathways of exposure are secondary pathways, like food contaminated by the soil, or fish contaminated by the surface water. I would recommend including a diagram depicting these primary and secondary exposure pathways, and may be include a discussion of the conditions when the secondary exposures might become significant relative to the primary. Most likely, the secondary exposure pathways cannot occur without the primary ones.

Response 2:

We present a diagram of the various exposure pathways in Figure 1.1 on page 4 of Chapter 1 that shows the sources of contamination for the secondary pathways. We do not consider exposure, other than inhalation, from airborne chemicals unless the chemical is subject to deposition. Significant exposure occurs following deposition of a subset of Hot Spots chemicals that are semi- and non-volatile onto surface water, soils, edible plants (both food, pasture and animal feed), and through ingestion of breast milk. We note that examining both direct inhalation and indirect noninhalation exposure pathways reveals the full extent of exposure to airborne emissions.
In general, there is a higher potential for indirect exposure to chemicals which tend to bioconcentrate or bioaccumulate (e.g., lipophilic semi-volatile organics), or otherwise accumulate in the environment (e.g., metals) because they are not biodegradable. Semi-volatile organic and metal toxicants can be directly deposited onto surface waters, soil, leaves, fruits and vegetables, grazing forage, and so forth. This is particularly important when these chemicals are associated with particulate matter. Cows, chickens, and other food animals can become contaminated through inhalation, and ingestion of contaminated surface water, pasture, feed and soil. Fish can become contaminated via bioconcentration from water and bioaccumulation from their food. Produce can become contaminated via root uptake from soils and direct deposition. Thus, humans can be exposed through ingestion of contaminated meat, fish, produce, water and soil, as well as from breathing contaminated air, and via dermal exposure. In addition, nursing infants can be exposed via breast milk.

Comment 3:

There is a recommendation in this document, that for facilities that are also under CERCLA/RCRA, risk assessment requirements under those programs also need to be considered. I would recommend a comparison and/or discussion between the Risk Assessment approaches from this Hot Spot document to the CERCLA/RCRA site risk assessment, especially for all common pathways of

exposures and exposure factors. Any different assumptions for pathways and exposure factors between the different programs need to be highlighted and explained, and specific recommendations for which one to be used explicitly laid out.

Response 3:

It would be a resource intensive exercise to compare the CERCLA/RCRA approach to the Hot Spots guidance. Such a discussion is outside the scope of this document.. . Although there is some overlap, the respective models are different because CERCLA/RCRA addresses hazardous waste sites and the Hot Spots program addresses airborne emissions from stationary facilities. The risk assessment paradigms reflect these different needs.

The easiest way for risk assessment innovations to be shared between programs is for programs to adopt workable approaches from other programs when they update their risk assessment models.

Comment 4:

I also recommend a separate Section to discuss the potential cumulative health risk assessment if one or more of the direct/indirect potentially exist near a Hot Spot facility. A discussion on the increasing magnitude of the exposure would be particular revealing, when more than one exposure pathway is considered. This is especially true if there is deposition on soil and surface water in a rural area, where both soil and surface water contamination can lead to home food, drinking water and fish ingestion exposure pathways.

Response 4:

The cumulative impact from multiple chemical exposures and from multipathway chemicals is discussed in the other approved Air Toxics Hot Spots Technical Support Documents for cancer and noncancer risk assessment, and is presented in detail in the *Hot Spots Guidance Manual for Preparation of the Health Risk Assessments*. This is the manual most risk assessors will refer to, as the Technical Support Document for Exposure Assessment and Stochastic Analysis mainly addresses how the variates for each exposure pathway were developed. Nevertheless, we will consider adding a paragraph in the Introduction that briefly discusses the cumulative assessment to cancer and noncancer chemicals from multiple chemical exposures.

Similarly to the U.S.EPA, it is our risk assessment practice to add the hazard quotients for the same pathways for chronic and now 8-hour RELs, for the same organ system. The inhalation and oral hazard quotients for the same organ system are also added. The hazard quotients for acute health impacts are added to give the overall hazard index for the organ system. Cancer risk for all

chemicals is added for both inhalation and oral carcinogens. Thus, the cumulative noncancer and cancer impacts are assessed in Hot Spots risk assessments.

Comment 5:

I would also recommend doing an analysis on HARP to see the impact on the risk assessment between the current guidelines and the new proposed ones in this Document.

Response 5:

This type of analysis should be possible when the ARB programs the new risk assessment model into a new version of the Hot Spots Analysis and Reporting Program (HARP). The results from the previous version of HARP can then be compared with the results from the new version of HARP.

Chapter 2 Comments and Responses

Comment 6:

(Page 2-11: Table 2.1) Under I2, rail yards and truck depots are included, but not airports, either large or municipal, or ports (Ports of LA and Oakland HRA are cited as examples on page 2-21). Please include explanation for exclusion of these sources as hot spots. Are parking garages considered as part of these hot spots for their car exhaust potential?

Response 6:

Rail yards, airports, and ports are under federal jurisdiction and therefore not subject to the Hot Spots Act. Parking garages are not considered because the sources of pollution are mobile sources and mobile sources are addressed under different California programs. The statute describes the general types of facilities covered under the Act.

Comment 7:

(Page 2-13, Section 2.5) If possible, please elaborate as to which of the Screening vs. Refined Analysis might be appropriate to be used in each of the 4 Tier Risk Assessments.

Response 7:

The Districts are responsible for approving the modeling protocols to be used in Hot Spots risk assessments. It is possible that the District would permit the use of screening procedure for a Tier 1 risk assessment in order to demonstrate that

the facility did not pose a threat to public health under worst case meteorological conditions. Since the purpose of Tiers 2 through 4 is to refine estimates of risk, it is likely that refined air modeling would be used in preference to a screening procedure that would tend to overestimate ground level air concentrations.

Chapter 3 Comments and Responses

Comment 8:

Page 42, Table 3.25: the values for the mean and 95% of the three methods included are significantly different from each other. I would recommend a further characterization on the uncertainty/variability of the default estimates for this parameter as compared to the other parameters used in the exposure calculation. It would be beneficial to have a summary table of all point estimates with their 95% values for all exposure factors in the exposure equation for each pathway. This would also provide a logical basis to select what needs to be improved from tier to tier risk assessment, i.e. it's more effective to try to improve some exposure factors with higher uncertainty/variability than those that are better defined. This comment would also apply for the age distribution of the breathing rate: a discussion on the uncertainty/variability of the age distribution of the breathing rate versus that of the factors would be beneficial, so as to provide a better characterization of the default assumptions.

Response 8:

There is considerable qualitative discussion of the uncertainties of the various methods in Chapter 3, as well in other chapters. There is currently a summary of all point estimates presented together in Chapter 5 of the Hot Spots Guidance Manual for Preparation of the Health Risk Assessments. This chapter, *Exposure Assessment – Estimation of Concentration and Dose*, brings together all the formulas and point estimates for every exposure pathway. This is the manual most risk assessors will refer to, as the Technical Support Document for Exposure Assessment and Stochastic Analysis mainly addresses each specific exposure variate by chapter and how each exposure variate were developed. The Hot Spots Guidance Manual for the Preparation of Risk Assessments will be updated when the final version of the Exposure Assessment and Stochastic Analysis Document is endorsed by the Scientific Review Panel and adopted by OEHHA.

OEHHA presents the percentiles, and statistical parameters, of the data where the data are available to assess variate variability. In addition, we present the best fit parametric model for these data which can be used in Monte Carlo analysis.

Finally, we do not require that th risk assessor use the 95th percentile for every variable in a multi-pathway assessment. Rather, the top 3 driving pathways are

assessed at the high end intake and the remaining pathways are assessed at average intake.

Comment 9:

Page 44, Table 3.26: I would like to point out that by using the DLW for the Age 0 < 2, and a mean of all the studies for all other age groups for the long term daily estimate for chronic risk assessment would generate a higher High end L/kg-day value for the 2 <9 age group than the 0 < 2 age group, which is against the decreasing trend observed for the mean value and all other estimates. This behavior is also observed in Table 3.27, for higher than 80% percentiles. Please provide some physiological explanation if possible.

Response 9:

It is physiologically implausible that high end (95^{th} percentile) breathing rates on a per kg body weight basis would be higher in the age 2<9 group compared to the 0<2 group. The total caloric intake method (CSFII) method is presumed to overestimate the upper percentiles because two days of survey data fails to properly characterize typical intake. As intraindividual variability increases relative to interindividual variability, the overestimation increases with this method. It is likely that the MET method also overestimates the upper percentiles of the breathing rate distribution for some age groups, according to Stifelman's (2007) analysis of the range of sustainable activities. Therefore averaging the three methods for the 2<9 group is likely to overestimated the upper percentiles of the 2<9 group.

A limited sample size of 40 for the 0<2 group in the DLW study makes the estimation of 95^{th} percentile less certain, although the repeated measures of two weeks per measure every three months is certainly a rare and admirable approach to characterizing typical breathing rates. In response to this comment, OEHHA re-evaluated our approach and has decided in the interests of a consistent approach for each age group to average the DLW method and the total caloric intake method (CSFII) for all age groups, including 0-<2 yrs, and not to average in the MET method, which has more uncertainty than the other methods. We have added discussion to the text explaining this.

We are using only the DLW and CSFII methods in part because we have individual data for these approaches that we can use to fit our specific age groups. This will average the CSFII method that has known methodological reasons that probably overestimate the upper percentiles, with a method that may tend to underestimate the upper percentiles in some age groups due to a less than representative sample for the general population. The 0 < 2 estimated breathing rate in terms of L/kg-body weight will thus be higher than the 2 < 9 age group for both the mean and 95^{th} percentile.

Chapter 4 Comments and Responses

Comment 10: Page 4, Section 4.2.2: please discuss how the choice of 18 kg as a default value for 0-9 years might influence the results (i.e. overestimation or underestimation for what specific age group), also the value of 63 kg seems to be much lower than the EPA value of 80 kg for adults (Exposure Factors Handbook, EPA 2011). Please explain this choice of value. How do these assumptions fall in with the values used in the Table 4.19?

Response 10:

We thank the commenter for pointing out this discrepancy. The paragraph has been revised to reflect the draft body weights for the proposed age groupings, namely age groups of 0<2, 2<9, 2<16, 16<30 and 16-70.

Comment 11:

Page 40, Table 4.19: please provide application of the values presented in this table. Under what specific exposure scenarios would the 2<6, 2<9, and 2<16 be used? How would each range be picked for any particular exposure scenarios?

Response 11:

Section 4.2.2 has been revised to explain the need for the age groupings. The exposure duration scenarios evaluate the first 9, 30 and 70 years of an individual's life. The evaluation of the 9, 30 and 70 year exposure durations represent approximately the mean, 90th and lifetime of residence time. The evaluation of the 0 to <2, 2 to <9,, 9 < 16 and 16 to <30 and 30 to 70 age groupings are needed in order to properly estimate cancer risk for the age ranges as specified in *The Technical Support Document for Cancer Potency Factors: Methodologies for Derivation, Listing of Available Values, and Adjustments to Allow for Early Life Stage Exposures* (OEHHA, 2009).

Chapter 5 Comments and Responses

Comment 12:

The recommendations in Table 5.6 did not go into any clarification on how to apply these values. If the 0-6 months values are selected for that age group, would the 0-12 months values be used for the 6-12 months age group? For the 0-12 months, under what exposure scenarios would each set of values be used?

Response 12:

How to apply the variates in Table 5.6 is explained on the first page of Chapter 5. Fully breastfed infants are those that receive breast milk as the primary, if not

sole, source of milk, and that this category encompasses three specific patterns of breastfeeding. Thus, the term “fully breastfed” is probably most often applied to the entire lactation period (0-12 months). For example, an infant who was exclusively breastfed for the first 6 months, then predominantly breastfed from 6 through 12 months, would be considered fully breastfed for the lactation period. We use the term “almost exclusively breastfed” particularly for the common practice of exclusive breastfeeding during the day with a small bottle of formula fed at night. OEHHA will clarify under Table 5.6 when each exposure scenario applies.

Comment 13:

From Table 5.7, the values for the 90% and 95% for the stochastic distribution seem to be lower than those for both the 0-6 months and 0-12 months point estimates. Please comment.

Response 13:

The 90% and 95% percentiles in Table 5.7 are the same as the 90% and 95% point estimates for fully breastfed infants over the first year in Table 5.6. This is expected to be the most common point estimates used in Table 5.6 when describing exposure to breastfeeding infants. The 0-6 month point estimates the Commenter is referring to appears be the ones in Table 5.6 for those infants fully breastfed over the first 6 months. These intake values are higher because infants 0-6 months of age are more often exclusively breastfed for the first 6 months, then predominantly breastfed from 6 through 12 months. The 0-12 month point estimates the Commenter appears to be referring to is for the exclusively breastfed infants in Table 5.6 in which breast milk is the sole source of calories for the first 12 months. The intake by these infants would be higher than those fully breastfed. Table 5.7 will be revised to note that the stochastic results are for fully breastfed infants.

Chapter 6 Comments and Responses

Comment 14:

This Section presented a thorough analysis of the Dermal Exposure Assessment for the Soil pathway. It also provides the comparison of the approach to other Cal EPA approaches (Pesticides, Hazardous Wastes). Since softwares are available for all the existing methodologies (Cal Tox, HARP, USEPA RSL etc…), I would recommend running a comparison between this draft guidelines and the existing ones, and include a discussion as to whether or not by going to the next level of details on many exposure factors, the results would turn out to be more or less conservative, and by how much. This comparison and discussion would be valuable especially in light of comparing any new Risk Assessment to an existing ones. A particular interesting comparison would be between the assumptions of

warm, cold and mixed vs the US EPA typical activity based specific dermal exposure assessment.

Response 14:

While it would be interesting to see the differences between the various models, OEHHA lacks the resources to run the analyses. When the new version of HARP is programmed with the new risk assessment model, the results can be compared with the current version of HARP results. The Air Resources Board is helping re-programming HARP with the n values and method after the peer review of these exposure guidelines. This will allow comparison of our previous model for dermal exposure and our proposed new method.

Comment 15:

It is interesting that in Section 8 (comments below), exposure to surface water near a facility as a drinking water source is the main drinking water pathway, but the exposure via the dermal pathway through swimming or playing in the same contaminated surface water bodies is not considered. Please provide a discussion on this issue.

Response 15:

OEHHA does not consider absorption of chemicals dissolved or deposited into water while swimming, bathing, or showering to be significant enough to include for exposure scenarios under the airborne release scenario considered in the "Hot Spots" program. An assessment performed for the first Exposure Document in 2000 found the risk from this pathway to be so low compared to other pathways that it was not included in that document. The same is true for the current proposed revisions of the Exposure Document. A brief statement why dermal exposure via contaminated water is not included is in the first paragraph of Chapter 6.

This is a good example of the reasons why different programs require different risk assessment models. The swimming, bathing, or showering can be a quite significant source of exposure with ground water contaminated by hazardous waste sites or leaking underground storage tanks.

Chapter 8 Comments and Response

Comment 16:

Another pathway for water intake is the potential indirect contamination of the groundwater from soil contamination, and if the groundwater is used as a source of drinking water, then this indirect pathway should be considered or discussed. In the EPA Superfund Regional Screening Levels calculation, this indirect

contamination from the soil to the groundwater is usually a significant exposure source. Since secondary exposure pathways due to soil contamination were considered for food intake and dermal, I would recommend including at least some discussion here on this pathway. In my general comments above, grouping the exposure pathways between direct (or primary) and indirect (secondary) will allow a clear presentation as to why any group of exposure pathways are considered in a specific risk assessment.

Response 16:

Contamination of ground water from Superfund sites or leaking underground storage tanks is common and appropriate to consider when evaluating such sites. The Hot Spots program considers contaminated soil but the soil is contaminated through airborne toxicants being deposited onto soil rather than chemicals being spilled or disposed of directly onto soil. It is unlikely that chemical concentrations deposited onto the surface of soils could build up to the point where significant contamination of ground water would occur particularly because most the toxicants are either lipophilic semivolatile organics or ionic heavy metals, that have a tendency to bind to soil minerals or organic material. Such toxicants tend to have limited mobility in most soils. If enough of a toxicant was deposited onto the soil to create a significant risk in absolute terms from groundwater contamination, the risks from inhalation and other noninhalation pathways would so large that the relatively small contributions of risk from ground water contamination would be dwarfed.

This again illustrates that different programs need different risk assessment models. Pathways are included in a Hot Spots risk assessments if (1) the physical chemical properties of the chemical allow significant exposure, and (2) the pathway is completed at the specific site. For example, exposure to arsenic through deposition on leafy vegetables would not be considered if there were no home grown produce. Prior to the previous version of this guidance we discussed these issues with both U.S.EPA Region 9 and Cal/EPA's Department of Toxic Substances Control. That is the reason we refer the reader to the RCRA/CERCLA risk assessment guidelines if they are evaluating a hazardous waste site.

Chapter 9 Comments and Response

Comment 17:

This is another indirect exposure pathway, similar to the one Food one considered in Section 7. See my general comments and comments in Section 6-8 for recommendation on grouping of exposure pathways. The contribution of both Food and Fish consumption might be particularly important for any rural community using their home grown/local sources as main subsistence.

Response 17:

OEHHA agrees that the fish consumption pathway could be an important contributor to exposure, particularly for subsistence fishers. We highlight this fact in paragraph 2 of chapter 9. However, note that this pathway has only been applied in a few risk assessments, and only applies to the subset of chemicals that are semi- or non-volatile. It does not apply to the majority of Hot Spots chemicals that are VOCs that are not expected to be contaminants of freshwater bodies from sources that emit airborne VOC pollutants under the Hot Spots program.

Comments and Response from EPA (Jacqueline Moya)

General Comments and Responses

Comment 18:

I suggest organizing the studies under each exposure factor in either chronological order or in some other logical fashion (e.g., order of importance). This will improve the flow of the document.

Response 18:

We will look at the organization of the studies for each variate and see if we can improve the order.

Comment 19:

There is a discrepancy on the age groups that are evaluated under each factor. On page 1-6, it lists the age groups to be evaluated under the Hot Spot program (i.e., 0 to <2 years; 2 to <9 years; 9 to<16 years; 16 to <30 years; and 30 to 70). For many of the factors the data are presented for 0 to<2 years; 2 to < 9 years and 2 to <16 years (emphasis added). This seems like a typo, but it is repeated so many times throughout the document that it made me think that it may not be a typo. Food consumption values, activities, and behaviors for a 2 year old would be different than those of a 16 year old. Therefore, it may not be appropriate to lump these age categories. This needs to be clarified.

Response 19:

The age group of 9<16 is indeed a typo on page 1-6. We thank the commenter in pointing this out. The correct age group is 2<16 years;, in addition to 0<2, 2<9, 16<30 and 16-70 years, which reflect the age groupings used for assessing cancer risk. In addition, in some cases age groupings by estimated home residency duration is discussed in various chapters. Home residency durations are 9 years for the central tendency and 30 years for the 90^{th}-95^{th} percentile, with

70 years as representing lifetime. Thus, in some cases, presentation of age groups of 9 to <16 and 30 to 70 are included. OEHHA will clarify these age groups in the chapters (i.e., groupings used to estimat cancer risk using the age sensitivity factors, or groupings based on home residency duration) in order to avoid confusion.

Comment 20:

The report cites the 2008 Child-specific Exposure Factors Handbook. Although I understand that this report was prepared before the 2011 Exposure Factors Handbook was published, some recommendations have changed and should be reviewed before the final report gets published.

Response 20:

OEHHA will review the 2011 Exposure Factors Handbook and make revisions where needed. However, some of the exposure factors in the revised 2011 handbook have already been incorporated into OEHHA's draft Exposure Document because the US EPA factors had been presented elsewhere before the 2011 version had been released.

Comment 21:

The document recommends doing the Age-dependent Adjustment Factors (ADAFs) of 10× and 3× depending on the age for carcinogenic effects. I believe that EPA's recommendation is to apply these ADAFs for carcinogens with a mutagenic mode of action. Is OEHHA applying ADAFs to all carcinogens?

Response 21:

Yes, OEHHA is applying the ADAFs to all the Hot Spots carcinogens. The justification for this is presented in the *Technical Support Document for Cancer Potency Factors: Methodologies for derivation, listing of available values, and adjustments to allow for early life stage exposures* endorsed by the Scientific Review Panel and finalized in May 2009.

Chapter 3 Comments and Responses

Comment 22:

In your email, you mentioned that there is a peak for the 2 <9 years old. I don't see the peak in slide #17 from your email. I see a decrease in inhalation rates per unit of body weight with age.

Response 22: Please see the response to comment 9.

Comment 23:

Table 1 shows that the values from EFH and OEHHA are not that much different. They should be similar since they come from the same data sets. The only difference is that for the 0<2 years, OEHHA relies only on Brochu et al. 2006 and EFH uses four studies.

Table 1. Recommended Mean Long-Term Daily Breathing Rates from OEHHA and EFH (L/day)

Age	0<2	2<9	2<16	16<30	16<70
OEHH	5.	11	13.	15.	15
EFH	6.7	11.0	15.2[b]	15.9	15.6

[a] **Should it be 9<16 years?**

[b] Value for 11<16 years. The value for 2<16 years would be 12.5 L/day.

Response 23:

Specifically, the DLW data on which the public review draft OEHHA 0<2 year age group breathing rates were based on is the published study by: *Butte NF, Wong WW, Hopkinson JM, Heinz CJ, Mehta NR and Smith EO (2000). Energy requirements derived from total energy expenditure and energy deposition during the first 2 y of life. Am J Clin Nutr 72(6): 1558-69*. OEHHA re-evaluated our approach for combining different breathing rate methods for estimation of our age group breathing rates. Please refer to Response 9 above for clarification.

The OEHHA 2<16 year age group in Table 1 is correct in this instance, and does not represent a 9<16 year age group.

Chapter 4 Comments and Responses

Comment 24:

The recommendations need to clarify if they refer to soil and dust ingestion or only soil. I believe that they are soil and dust combined, but it is not clear.

Response 24:

Soil ingestion refers to both dust and soil ingestion. We will clarify that in Chapter 4.

Comment 25:

The studies are not organized in any logical order.

Response 25:

The studies are not organized by the year they were published as in the U.S. EPA documents but by the key authors and their co-workers. For example: Calabrese and co-workers published numerous studies, some under "Calabrese" and others under "Stanek" over a period of almost 20 years. We feel it is easier for the reader to see these studies together instead of mixing them up with studies from other authors.

Comment 26:

Why is table 4-18 not including the 3rd trimester as in table 4-19?

Response 26:

Table 4-18 now includes the 3rd trimester.

Comment 27:

Although EPA's recommendation for the upper percentile soil ingestion is 200 mg/day, OEHHA's recommendation of 400 mg/day is also within the ranges of upper percentiles observed in the literature. However, I think it may be misleading to characterize it as a 95^{th} percentile because the data do not support this kind of precision. Characterizing it as a "high end" value may be more appropriate.

Response 27:

OEHHA's recommendation of 400 mg/day is based not wholly on the EPA's recommendation. We used other studies in which the 95th percentile were calculated. For example, Xue et. al (2007) calculated the 95th percentile hand-to-mouth estimates from various studies, which we used in our extrapolation to different age groups.

Chapter 5 Comments and Responses

Comment 28:

Recommendations are provided for human milk intake for the first year of life. I think that it may be more appropriate to evaluate infants by finer age groups since younger infants are more likely to be exclusively breast fed than older infants.

Response 28:

OEHHA covers the most common scenarios for infant breastfeeding behaviors, which typically range from the first 6 months to a 1 yr. Scenario 1 (see Table 5.6) assumes exclusive breastfeeding for the first 6 months, then fully breastfed from 6-12 months. Scenario 2 assumes exclusive breastfeeding for the entire first year of life. Finally, scenario 3 assumes that the infant is fully breastfed for the first 6 months of life. OEHHA felt that finer age groupings were not necessary because the durations are small (on the order of months) when compared to a 70 year lifespan. The difference, for example, for breast milk intake at 1 month of age compared to 6 months of age is less than two-fold when expressed in g/kg body weight-day (see Table 5.6).

Chapter 6 Comments and Responses

Comment 29:

Table 6-2 presents total body surface area by age groups from NHANES 1999-2004. It should be indicated that these are mean values. The 2011 EFH presents mean and 95th percentiles from NHANES 1999-2006 data.

Response 29:

The Table was revised to specify that total body surface distributions (including the mean) are presented. OEHHA did not have access to the NHANES 2006 data at the time the dermal chapter was written. However, the recently updated NHANES body surface data are not expected to significantly alter the dermal exposure variate outcome.

Chapter 7 Comments and Responses

Comment 30:

OEHHA conducted analysis of NHANES food consumption data. Are the values presented per capita values or consumers only? How were mixtures handled? Were recipe files created?

Response 30:

The values represent consumer only values. We will clarify this in the text of Chapter 7

Comment 31: What is the rationale for combining fruits and vegetables into one category called “produce?”

Response 31:

Fruits and vegetables (produce) are combined into broad categories according to the mechanism through which contamination takes place. For example, plums and broccoli are both exposed through deposition onto edible surfaces. Homegrown produce would encompass both fruits and vegetables which are then subdivided into the root, leafy, exposed and protected categories depending on the mode of contamination. Some of the categories such as leafy produce would only contain vegetables. The protected category would include, for example, pumpkins and oranges

Comment 32:

I compared some of the values derived by OEHHA with the values presented in the 2011 EFH from the same data set and found some discrepancies. For example, the mean intake of total meats in the EFH for children 0 < 2 years is 2.6 g/kg-day. The mean intake for the same age group in table 7.3.2 is 11.3 g/kg-day, estimated by adding beef, pork, and poultry. In addition, for some foods it may not be appropriate to lump the young infants with the toddlers. Meat ingestion is one example. The consumption of meat for infants up to 6 or 8 months is probably zero.

Response 32:

Consumers-only meat intake will be less than the intake obtained by adding up the separately determined beef, pork, and poultry consumptions rates. In effect by adding beef, pork and chicken together, three days of beef, pork or chicken are added together. When consumer-only total meat intake is determined, the daily intake of meat is determined. With only two days of survey data it is impossible to determine typical intake of chicken, beef or pork for each individual. This is the data that would be ideal for long term risk assessment. The typical consumption rate is thus likely to be overestimated using the survey methodology. The home raised chicken pathway has rarely if ever been a completed pathway in a Hot Spots risk assessment. The home raised beef and pork has never been a completed pathway in a Hot Spots risk assessment. The meat intake rate is reduced by applying the fraction of home raised chicken, beef, or pork.

Comment 33:

Tables with intake rate data need to flag those values that may be less reliable due to sample size.

Response 33:

We will put a statement in the Introduction acknowledging that sample sizes of less 40 have considerable uncertainty.

Chapter 8 Comments and Responses

Comment 34:

Table 8-10 need to flag those values that may be less reliable due to sample size.

Response 34:

See Comment 33 above.

Chapter 9 Comments and Responses

Comment 35:

Table 9.2 should indicate that these are freshwater consumption rates.

Response 35:

The Table was revised to show that all studies presented in the Table were estimates of freshwater sport-caught fish consumption rates.

Comment 36:

Page 9-14 indicates an adult body weight of 88.3 kg. Other parts of the report use 80 kg.

Response 36:

The adult body weight of 88.3 kg refers to the mean body weight of males >20 years of age (as specified in Table 10.1, the body weight chapter). When fish consumption data from other studies is presented only by gender in g/day, OEHHA used 88.3 kg body weight for males and 74.7 kg body weight for females to determine the fish consumption rate normalized by weight. If the data combined adult males and females, the 80.0 kg body weight adjustment was used. We thank the Commenter for pointing this out because there's a discrepancy in the last paragraph on Page 9-14 in which 80.0 kg was used erroneously to normalized fish consumption by body weight for males only. The body weight used should have been 88.3 kg and has been corrected.

Comment 37:

Section 9.8.1; Are these recommendations for both marine and freshwater consumption rates?

Response 37:

Section 9.8.1 was revised to indicate the recommendation is for freshwater sport fish consumption rates. Under the Hot Spots program, these are the water bodies of concern, as marine waters are not expected to accumulate/concentrate chemical air emissions from a single facility that deposit onto the marine water body surface.

Comment 38:

Fish consumption is another example of a food item for which infants < 6 months will have a zero value. Age groups should be adjusted accordingly.

Response 38:

For the 0<2 year age group, little or no fish consumption by the infant is expected from birth to one year of age. OEHHA notes in Section 9.8.1 that for the 0<2 age group, no fish consumption is expected in the first year, and fish consumption during the second year was assumed proportional on a gram per kg body weight basis to that of older children and adults. Thus, the fish consumption rate is based on the mean body weight of children during the second year (11.4 kg for 1<2 year age group) and divided by two to represent the first 2 years after birth. The resulting mean and high-end fish consumption rates are 2.1 and 6.6 g/day, respectively.

For the fetus, exposure can occur via the mother's consumption of fish during the third trimester of pregnancy. Fetal exposure during the third trimester via fish consumption by the mother is also taken into account in the final determination of the point estimate values presented in Section 9.8.

Chapter 11 Comments and Responses

Comment 39:

Page 11-5 describes the data used to derive employment tenure. It is unclear if the numbers represent the amount of time spent at the current job or the time spent at the previous job. If it is the former, then the numbers may be an underestimate of the total employment tenure.

Response 39:

OEHHA analyzed the most recent set of the Census Bureau's Survey of Income and Program Participation (SIPP) job data and calculated job duration using job start and end dates, and used an end date of December 31, 2008 for those who were still employed at the same job. We ran frequency distributions of years on the job and years on the job by age using the FREQUENCY and SURVEYFREQ procedures in SAS version 9.1.3 (shown in Table 11.2).

The main limitation using SIPP data to estimate occupational duration at a single location is that the job tenure question includes for years spent with current employer (i.e., the job is still in progress). This was also the case for another survey summarized in Chapter 11 called the Current Population Survey (CPS). However, the CPS survey covers the entire span of working years from age 16 to 70+ years. In particular, the oldest groups of participants represent those workers at or near retirement age with a full work history. In addition, Nardone et al., (1997) observed that similar job tenure percentiles were obtained when comparing young workers from both the CPS and NLSY79 surveys (also summarized in Chapter 11).

Comparison of this survey with the SIPP shows that for the first 20 years of employment beginning at age 15 or 16 years, the tenure percentages are almost identical. The CPS shows that 10.3 percent of participants beginning at age 16 are still with their current employer after 20 years. The SIPP (Table 11.2) estimates 10.54 percent of participants are still with their current employer after 20 years. Thus, OEHHA is confident that there is no appreciable underestimation of total employment tenure.

Comment 40:

Table 11.2; the last two columns have exactly the same label. What is the difference?

Response 40:

Both columns present the same data; the only difference is that the first of these columns shows an increasing frequency trend (starting at 0% cumulative total at start of employment) and the second column shows a decreasing trend (starting at 100% cumulative total at start of employment). This is how the data were presented by the SIPP.